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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,126	06/06/2005	Shunsuke Kuroiwa	442P097	2218
42754	7590	05/14/2008		
Nields & Lemack 176 E. Main Street Suite #5 Westboro, MA 01581			EXAMINER JAISLE, CECILIA M	
			ART UNIT	PAPER NUMBER
			1624	
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			05/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,126

Applicant(s)

KUROIWA ET AL.

Examiner

CECILIA M. JAISLE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 10, 12 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 9, 10, 12 and 16-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

Restriction

821.03 Claims for Different Invention Added After an Office Action [R-3]

Claims added by amendment following action by the examiner, MPEP § 818.01, § 818.02(a), to an invention other than previously claimed, are treated as indicated by 37 CFR 1.145.

37 CFR 1.145 Subsequent presentation of claims for different invention

If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant is required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in 37 CFR §§ 1.143 and 1.144.

Amended claims 1-7, 9, 10 and 12 and newly submitted claims 16-25 are directed to an invention that is independent or distinct from the inventions originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 9, 10, 12 and 16-25, drawn to a method for treating a tumor, classified in class 514, subclass 248, *inter alia*.
- II. Claim 15, drawn to certain substituted 3-phenyl-cinnoline compounds, classified in class 544, subclasses 235, 236, *inter alia*.

The inventions are independent or distinct for the following reasons. Inventions I – II, respectively, are not obvious variants of each other, i.e., a reference that could be used to reject one invention could not be used to reject another invention; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, Group I methods are distinct from Group II compounds, because Group II would be useful for treating bone deficit conditions (US 5919808).

In the instant case, the related inventions of Groups I – II do not overlap in scope because the inventions of Groups I – II have acquired separate status, as evidenced by their separate classification in the art. Although these Groups may partially have the same patent classification, they would each require a separate search in the literature. Therefore, it would impose an undue burden on the examiner to search and examine these distinct inventions together.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries; see MPEP § 808.02);

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(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-7, 9, 10, 12 and 16-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections Under 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 15 is rejected under 35 USC 103(a) over Altomare, et al. (J. Med. Chem., 1998, 41, pp. 3812-3820)(cited by Applicants)describing condensed pyridazines of Formulae 28 and 29 (page 3813, col. 2).

The Altomare compounds are useful for inhibition of monoamine oxidase-B. The claimed compounds are homologs and/or position isomers of the Altomare compounds. Even though the claims exclude the Altomare compounds (i.e., not all R4 may be H), the claims include homologs and/or position isomers thereof.

Compounds of the present claims that are homologs and/or position isomers of Altomare would have been obvious to one having ordinary skill in the art at the time of the present invention for the expected utility of the Altomare compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds that are homologs and/or positions isomers and/or further suggested by the Altomare compounds, because such structurally related compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results.

An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.

In re Payne, 203 USPQ 245, 254 (CCPA 1979). *In re Papesch*, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1991) (discussed in MPEP § 2144) for an extensive case law review pertaining to obviousness based on close structural chemical compound similarity. See also MPEP § 2144.08, III.A.4(c). Compounds that are homologs (compounds differing by the successive addition of the same chemical group, e.g., by CH₃- groups) or positions isomers, as here, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 195 USPQ 426 (CCPA 1977). *Altomare* establishes a *prima facie* case of obviousness for the presently claimed compounds. Absent the presentation of verifiable data establishing the unobviousness of the claimed compounds over *Altomare*, this rejection is deemed sound.

Claim 15 is rejected under 35 USC 103(a) over Nagarajan, et al. (J. Med. Chem., 1976, 19, pp. 508-511) (cited by Applicants) describing a 5-oxo-1,4,5,6,7,8-hexahydrocinnoline of compound no. 14, Table I (page 509).

The Nagarajan compounds have central nervous system activity. The claimed compounds are homologs and/or position isomers of the Nagarajan compounds. Even though the claims exclude the Nagarajan compounds, the claims include homologs and/or position isomers thereof.

Compounds of the present claims that are homologs and/or position isomers of Nagarajan would have been obvious to one having ordinary skill in the art at the time of the present invention for the expected utility of the Nagarajan compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds that are homologs and/or positions isomers and/or further suggested by the Nagarajan compounds, because such structurally related compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results. See the discussion above for Altomare of the obviousness of isomers/homologs.

Claim 15 is rejected under 35 USC 103(a) over Petrie, et al. (erroneously previously cited as Orme, et al.), US 5919808, patented 19990706, describing RN 190436-31-8, 5(1H)-cinnolinone, 3-(4-chloro-3-methylphenyl)-4,6,7,8-tetrahydro-7,7-dimethyl- and RN 190436-38-5, 5(1 H)-Cinnolinone, 3-(4-bromophenyl)-4,6,7,8-tetrahydro-7,7-dimethyl-, useful for treating bone deficit conditions.

The claimed compounds are homologs and/or position isomers of the Petrie compounds. Even though the claims exclude the Petrie compounds, the claims include homologs and/or position isomers thereof.

Compounds of the present claims that are homologs and/or position isomers of Petrie would have been obvious to one having ordinary skill in the art at the time of the present invention for the expected utility of the Petrie

compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds that are homologs and/or positions isomers and/or further suggested by the Petrie compounds, because such structurally related compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results. See the discussion above for Altomare of the obviousness of isomers/homologs.

Response to Remarks of 02-14-2008

Due to Applicants' presentation of new claim 15, this claim is rejected under 35 USC 103(a) rather than 35 USC 102, as were the originally presented claims. Accordingly, Applicants' remarks do not apply to the present rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia M. Jaisle, J.D.

5/7/2008

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624